IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF DELAWARE

GARY RICKS, Derivatively On Behalf Of TRICIDA, INC., Plaintiff, vs. ROBERT J. ALPERN, DAVID BONITA, SANDRA I. COUFAL, DAVID HIRSCH, KATHRYN FALBERG, GERRIT KLAERNER, KLAUS R. VEITINGER, AND GEOFFREY M. PARKER, Defendants, -and- TRICIDA, INC., Nominal Defendant.	**Case No.:** **JURY DEMANDED**

VERIFIED SHAREHOLDER DERIVATIVE COMPLAINT

Plaintiff Gary Ricks ("Plaintiff"), by and through his undersigned counsel, derivatively on behalf of Nominal Defendant Tricida, Inc. ("Tricida" or the "Company"), submits this Verified Shareholder Derivative Complaint (the "Complaint"). Plaintiff's allegations are based upon his personal knowledge as to himself and his own acts, and upon information and belief, developed from the investigation and analysis by Plaintiff's counsel, including a review of publicly available information, including filings by Tricida with the U.S. Securities and Exchange Commission ("SEC"), press releases, news reports, analyst reports, investor conference transcripts, publicly available filings in lawsuits, and matters of public record. Plaintiff believes that substantial evidentiary support will exist for the allegations set forth herein after a reasonable opportunity for

discovery.

NATURE OF THE ACTTION

1. This is a shareholder derivative action brought on behalf of and for the benefit of the Company, against certain of its officers and/or directors named as defendants herein seeking to remedy Defendants (defined below) violations of Sections 10(b) and 21D of the Securities Exchange Act of 1934 (the "Exchange Act"), and their breaches of fiduciary duties and other wrongful conduct as alleged herein and that occurred from September 4, 2019 to the present (the "Relevant Period"). Defendants' actions have caused, and will continue to cause, substantial financial harm and other damages to the Company, including damages to its reputation and goodwill.

2. The Company was founded in 2013 and is headquartered in South San Francisco, California. The Company is a pharmaceutical company that focuses on the development and commercialization of its drug candidate, veverimer (TRC101), a non-absorbed, orally administered polymer designed as a potential treatment for metabolic acidosis in patients with chronic kidney disease ("CKD"). The Company completed a Phase 3, double-blind, placebo-controlled trial of veverimer in patients with CKD and metabolic acidosis.

3. On September 4, 2019, the Company announced that it had submitted a New Drug Application ("NDA") to the U.S. Food and Drug Administration ("FDA") under the Accelerated Approval Program for approval of veverimer for the treatment of metabolic acidosis in patients with CKD.

4. Throughout the Relevant Period, Defendants made materially false and misleading statements concerning the Company's business, operational, and compliance policies. Defendants made false and/or misleading statements and/or failed to disclose that: (a) the Company's NDA

for veverimer was materially deficient; (b) accordingly, it was foreseeably likely that the FDA would not accept the NDA for veverimer; and (c) as a result, the Company's public statements were materially false and misleading at all relevant times.

5. On July 15, 2020, the Company issued a press release announcing that, on July 14, 2020, it received a notification from the FDA, stating that as part of the FDA's ongoing review of the Company's NDA for veverimer: "the FDA has identified deficiencies that preclude discussion of labeling and post marketing requirements/commitments at this time." The Company stated that "[t]he notification does not specify the deficiencies identified by the FDA."

6. On this news, the Company's stock price fell $10.56 per share, or 40.31%, to close at $15.64 per share on July 16, 2020.

7. Then, on October 29, 2020, the Company announced an update on its End-of-Review Type A meeting with the FDA regarding the veverimer NDA, advising investors that the Company "now believes the FDA will also require evidence of veverimer's effect on CKD progression from a near-term interim analysis of the VALOR-CKD trial for approval under the Accelerated Approval Program and that the FDA is unlikely to rely solely on serum bicarbonate data for determination of efficacy." Also, the Company disclosed that it "is significantly reducing its head count from 152 to 59 people and will discuss its commitments with vendors and contract service providers to potentially provide additional financial flexibility."

8. On this news, the Company's stock price fell $3.90 per share, or 47.16%, to close at $4.37 per share on October 29, 2020.

JURISDICTION AND VENUE

9. This Court has subject matter jurisdiction pursuant to 28 U.S.C. § 1331 because Plaintiff's claims raise a federal question under Section 10(b) of the Exchange Act, 15. U.S.C. §

78j(b), and Section 21D of the Exchange Act, 15 U.S.C. § 78u-4(f). Plaintiff's claims also raise a federal question pertaining to the claims made in the Securities Class Actions (defined below) based on violations of the Exchange Act.

10. This Court has jurisdiction over each defendant named herein because each defendant is either a corporation that conducts business in and maintains operations in this District or is an individual who has sufficient minimum contacts with this District to render the exercise of jurisdiction by the District courts permissible under traditional notions of fair play and substantial justice.

11. Venue is proper in this Court in accordance with 28 U.S.C. § 1391 because the Company's Certificate of Incorporation state:

> 9.1 Forum for Certain Actions.
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> (a) Forum. Unless a majority of the Board, acting on behalf of the Corporation, consents in writing to the selection of an alternative forum (which consent may be given at any time, including during the pendency of litigation), the Court of Chancery of the State of Delaware (or, if the Court of Chancery does not have jurisdiction, another state court located within the State of Delaware or, if no court located within the State of Delaware has jurisdiction, the federal district court for the District of Delaware) shall be the sole and exclusive forum for (i) any derivative action or proceeding brought on behalf of the Corporation, (ii) any action asserting a claim of breach of a fiduciary duty owed by any current or former director, officer or other employee of the Corporation to the Corporation or the Corporation's stockholders, (iii) any action asserting a claim against the Corporation or any of its directors, officers or other employees arising pursuant to any provision of the DGCL, this Certificate of Incorporation or the Bylaws (in each case, as may be amended from time to time), (iv) any action asserting a claim against the Corporation or any of its directors, officers or other employees governed by the internal affairs doctrine of the State of Delaware, or (v) any other action asserting an "internal corporate claim," as defined in Section 115 of the DGCL, in all cases subject to the court's having personal jurisdiction over all indispensable parties named as defendants.

PARTIES

Plaintiff

12. ***Plaintiff Gary Ricks*** ("Plaintiff") acquired the Company securities and will continue to hold Tricida shares throughout the pendency of this action. Plaintiff will fairly and adequately represent the interests of the shareholders in enforcing the rights of the corporation.

Nominal Defendant

13. ***Nominal Defendant Tricida*** is a Delaware corporation with principal executive offices located at 7000 Shoreline Court, Suite 201, South San Francisco, California 94080.

Director Defendants

14. ***Defendant Robert J. Alpern, M.D.*** ("Alpern") has served as a member of the Board since October 2013 and as Chairman of the Scientific Advisory Board from October 2013 through May 2018. Defendant Alpern is a member of the Nominating and Governance Committee.

15. ***Defendant David Bonita, M.D.*** ("Bonita") has served as a member of the Board since January 2014. Defendant Bonita is a member of the Audit Committee and Nominating and Governance Committee, and the Chair of the Compensation Committee.

16. ***Defendant Sandra I. Coufal, M.D.*** ("Coufal") has served as a member of the Board since July 2013 and as a member of the Scientific Advisory Board since August 2013. Defendant Coufal is a member of the Compensation Committee. Defendant Coufal is a co-founder and has served as a comanager of Sibling Capital Ventures LLC, an affiliate of one of the Company's principal stockholders, since 2013. Defendant Coufal was a co-founder and a co-manager of Sibling Capital, LLC from 2012 to 2016.

17. ***Defendant David Hirsch, M.D.*** ("Hirsch") has served as a member of the Board since July 2016. Defendant Hirsch is a member of the Audit and Compensation committees.

18. ***Defendant Kathryn Falberg*** ("Falberg") has served as a member of the Board since May 2018. Defendant Falberg is the Chair of the Audit Committee.

19. ***Defendant Gerrit Klaerner*** ("Klaerner") has served as a member of the Board since July 2013 and as Chief Executive Officer ("CEO") and President since August 2013. Defendant Klaerner is a defendant in the Securities Class Action (defined below).

20. ***Defendant Klaus R. Veitinger, M.D.*** ("Veitinger") has served as a member the Board since February 2014 and as the Chairman of the Board since September 2015. Defendant Veitinger is the Chair of the Nominating and Governance Committee. Defendant Veitinger has served as a Venture Partner with OrbiMed Advisors LLC, an affiliate of one of the Company's principal stockholders, since October 2007.

21. Defendants Alpern, Bonita, Coufal, Hirsch, Falberg, Klaerner, and Veitinger are herein referred to as "Director Defendants."

Officer Defendant

22. ***Defendant Geoffrey M. Parker*** ("Parker") has served as the Company's Chief Financial Officer ("CFO") and Senior Vice President ("SVP") at all relevant times. Defendant Parker is a defendant in the Securities Class Action (defined below).

23. The Director Defendants and Defendant Parker are collectively referred to herein as "Defendants".

THE COMPANY'S CORPORATE GOVERNANCE

24. As members of Board, the Director Defendants were held to the highest standards of honesty and integrity and charged with overseeing the Company's business practices and policies and assuring the integrity of its financial and business records.

25. The conduct of the Director Defendants complained of herein involves a knowing

and culpable violation of their obligations as directors and officers of Tricida, the absence of good faith on their part, and a reckless disregard for their duties to the Company and its investors that the Director Defendants were aware posed a risk of serious injury to the Company

DUTIES OF THE DIRECTOR DEFENDANTS

26. By reason of their positions as officers, directors, and/or fiduciaries of Tricida and because of their ability to control the business and corporate affairs of Tricida, the Director Defendants owed the Company and its shareholders the fiduciary obligations of trust, loyalty, good faith and due care, and were and are required to use their utmost ability to control and manage Tricida in a fair, just, honest, and equitable manner. The Director Defendants were and are required to act in furtherance of the best interests of Tricida and its shareholders.

27. Each director and officer of the Company owes to Tricida and its shareholders the fiduciary duty to exercise good faith and diligence in the administration of the affairs of the Company and in the use and preservation of its property and assets, as well as the highest obligations of fair dealing. In addition, as officers and/or directors of a publicly held company, the Director Defendants had a duty to promptly disseminate accurate and truthful information regarding the Company's operations, finances, financial condition, and present and future business prospects so that the market price of the Company's stock would be based on truthful and accurate information.

28. The Director Defendants, because of their positions of control and authority as directors and/or officers of Tricida, were able to and did, directly and/or indirectly, exercise control over the wrongful acts complained of herein, as well as the contents of the various public statements issued by the Company. Because of their advisory, executive, managerial and directorial positions with Tricida, each of the Defendants had access to adverse non-public

information about the financial condition, operations, sales and marketing practices, and improper representations of Tricida.

29. To discharge their duties, the officers and directors of Tricida were required to exercise reasonable and prudent supervision over the management, policies, practices, and controls of the financial affairs of the Company. By virtue of such duties, the officers and directors of Tricida were required to, among other things:

(a) Ensure that the Company complied with its legal obligations and requirements, including acting only within the scope of its legal authority and disseminating truthful and accurate statements to the SEC and the investing public;

(b) Conduct the affairs of the Company in an efficient, businesslike manner so as to make it possible to provide the highest quality performance of its business, to avoid wasting the Company's assets, and to maximize the value of the Company's stock;

(c) Properly and accurately guide investors and analysts as to the true financial condition of the Company at any given time, including making accurate statements about the Company's business prospects, and ensuring that the Company maintained an adequate system of financial controls such that the Company's financial reporting would be true and accurate at all times;

(d) Remain informed as to how Tricida conducted its operations, and, upon receipt of notice or information of imprudent or unsound conditions or practices, make reasonable inquiries in connection therewith, take steps to correct such conditions or practices, and make such disclosures as necessary to comply with federal and state securities laws;

(e) Ensure that the Company was operated in a diligent, honest, and prudent

manner in compliance with all applicable federal, state and local laws, and rules and regulations; and

(f) Ensure that all decisions were the product of independent business judgment and not the result of outside influences or entrenchment motives.

30. Each Director Defendant, by virtue of his or her position as a director and/or officer, owed to the Company and to its shareholders the fiduciary duties of loyalty, good faith, and the exercise of due care and diligence in the management and administration of the affairs of the Company, as well as in the use and preservation of its property and assets. The conduct of the Director Defendants complained of herein involves a knowing and culpable violation of their obligations as directors and officers of Tricida, the absence of good faith on their part, and a reckless disregard for their duties to the Company and its shareholders that the Director Defendants were aware or should have been aware posed a risk of serious injury to the Company.

31. The Director Defendants breached their duties of loyalty and good faith by causing the Company to misrepresent the information as detailed *infra*. The Director Defendants' subjected the Company to the costs of defending, and the potential liability from, the securities class action (and related lawsuits). As a result, Tricida has expended, and will continue to expend, significant sums of money.

32. The Director Defendants' actions have irreparably damaged Tricida's corporate image and goodwill.

THE FALSE AND MISLEADING STATEMENTS

33. The Relevant Period begins on September 4, 2019, when, during pre-market hours, the Company issued a press release announcing that it had submitted an NDA to the FDA under the Accelerated Approval Program for approval of veverimer for the treatment of metabolic

acidosis in patients with CKD. That press release also stated:

> The NDA submission is supported by data from Tricida's successful Phase 3 clinical trials that were recently published in back-to-back publications in The Lancet (March 2019 and June 2019).
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> "This submission under the FDA's Accelerated Approval Program could provide the first and only FDA-approved therapy to this underserved population of patients with chronic kidney disease and metabolic acidosis," said Gerrit Klaerner, PhD, Tricida's Founder, Chief Executive Officer and President. "We are grateful for the patients who participated in our clinical trials, our clinical investigators and the entire Tricida team who have made this journey possible. It is notable that the process from generating the idea to treat metabolic acidosis to the in-house discovery, development and NDA submission of veverimer was achieved in less than 6 years. We now look forward to the potential approval and launch of veverimer next year."

34. On November 14, 2019, the Company issued a press release announcing that the FDA had accepted the Company's NDA for veverimer. That press release also stated:

> In its correspondence, [the] FDA . . . stated that no filing review issues [with the NDA for veverimer] were identified. The FDA has assigned a Prescription Drug User Fee Act (PDUFA) goal date of August 22, 2020 and indicated that it is currently planning to hold a Cardiovascular and Renal Drugs Advisory Committee meeting to discuss the application.
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> The NDA submission is supported by data from Tricida's successful Phase 3 clinical trials that were recently published in back-to-back publications in The Lancet (March 2019 and June 2019).
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> "We are pleased that our application for veverimer was accepted for review under the Accelerated Approval Program and look forward to engaging with experts at an advisory committee meeting," said Gerrit Klaerner, Ph.D., Tricida's chief executive officer and president. "With a potential approval in August 2020, veverimer would be the first and only FDA-approved therapy for the chronic treatment of metabolic acidosis in patients with CKD. Our commercial team is targeting a successful launch with a full quarter of revenue in the fourth quarter of 2020."

35. That same day, the Company issued a press release announcing the Company's third quarter 2019 financial results. The press release listed as one of the Company's highlights:

> Announced separately today that the U.S. Food and Drug Administration (FDA) has accepted for review the company's New Drug Application (NDA) for veverimer under the Accelerated Approval Program. In its correspondence, FDA

> also stated that no filing review issues were identified. The FDA has assigned a Prescription Drug User Fee Act (PDUFA) goal date of August 22, 2020 and indicated that it is currently planning to hold a Cardiovascular and Renal Drugs Advisory Committee (CRDAC) meeting to discuss the application.

36. In addition, the press release quoted Defendant Klaerner, stating:

> "We are pleased that our application for veverimer was accepted for review under the Accelerated Approval Program and look forward to engaging with experts at an advisory committee meeting," said Gerrit Klaerner, Ph.D., Tricida's chief executive officer and president. "With a potential approval in August 2020, veverimer would be the first and only FDA-approved therapy for the chronic treatment of metabolic acidosis in patients with CKD. Our commercial team is targeting a successful launch with a full quarter of revenue in the fourth quarter of 2020."

37. That same day, the Company filed a Quarterly Report on Form 10-Q with the SEC, reporting the Company's financial and operating performance for the quarter ended September 30, 2019 (the "Q3 2019 10-Q"). In providing an overview of the Company, the Q3 2019 10-Q stated:

> In August 2019, we submitted a New Drug Application, or NDA, to the U.S. Food and Drug Administration, or FDA, seeking approval to market veverimer. We subsequently received the FDA's filing communication letter, or Day 74 Letter, which stated that our NDA had been accepted for review by the FDA under the Accelerated Approval Program and that a user fee goal date of August 22, 2020 had been set under the Prescription Drug User Fee Act. The Day 74 Letter also stated the FDA is currently planning to hold an advisory committee meeting to discuss the NDA, which we believe would likely occur in the first half of 2020.
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> Veverimer is an in-house discovered, new chemical entity, that we believe may effectively treat metabolic acidosis and slow the progression of kidney disease in CKD patients with metabolic acidosis.
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> We estimate that metabolic acidosis affects approximately 3 million CKD patients in the United States, and we believe that slowing the progression of CKD in patients with metabolic acidosis represents a significant medical need and market opportunity. If approved, we plan to commercialize veverimer in the United States initially using a nephrologist-focused sales force. To address markets outside of the United States, we plan to seek one or more partners with international sales expertise who can sell veverimer in target markets. We have an intellectual property estate that we believe will provide patent protection for veverimer until at least 2034 in the United States, the European Union, Japan, China, India and certain other markets. Tricida is led by a seasoned management team that includes a

> founder of Ilypsa, Inc. and Relypsa, Inc. Our management team has extensive experience in the development and commercialization of therapeutics, with deep expertise in developing polymers for the treatment of kidney-related diseases.

38. Appended to the Q3 2019 10-Q as an exhibit was a signed certification pursuant to the Sarbanes-Oxley Act of 2002 ("SOX") by Defendants Klaerner and Parker, attesting that, "[t]he information contained in [the Q3 2019 10-Q] fairly presents, in all material aspects, the financial condition and results of operations of the Company."

39. That same day, the Company hosted an earnings call with investors and analysts to discuss the Company's third quarter 2019 results (the "Q3 2019 Earnings Call"). During the scripted portion of the Q3 2019 Earnings Call, Defendant Klaerner stated:

> We are pleased to report that our veverimer NDA has been accepted for a review by the FDA under the Accelerated Approval Program with no filing review issues identified. The application is under review by the division of cardiovascular and renal products as a standard review designation and the PDUFA goal date of August 22, 2020. As a reminder, this filing acceptance under the Accelerated Approval Program underscores the fact that metabolic acidosis is a serious condition and as the veverimer, if approved, would address an unmet medical need.
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> The FDA has also indicated that they are currently – that they currently plan to hold an advisory committee meeting or AdCom to discuss the application. We anticipate the AdCom would likely occur in the first half of 2020 and we will know the topics of discussion closer to the meeting date.

40. When asked a question regarding why the FDA would want an Advisory Committee meeting, Defendant Klaerner responded:

> I've learned over the years not to speculate and I think we're obviously very excited to actually present our data. I think both from the perspective of standard review and the outcome, when you look at our program we are among the first to really utilize the accelerated approval path with a renal indication and when we had our pre-NDA meeting, I think we shared all the data with them that we had available, including the data beyond the surrogate. So again, I'm not speculating about any potential topics for the AdCom, but this is exciting. I mean I think not many people have had pursued a major disease-modifying renal indication under Subpart H.

41. On February 27, 2020, the Company issued a press release announcing the Company's fourth quarter and full year 2019 financial results. The press release included as one of the Company's highlights:

> The U.S. Food and Drug Administration (FDA) accepted for review, through the Accelerated Approval Program, Tricida's New Drug Application (NDA) for veverimer and has assigned a Prescription Drug User Fee Act (PDUFA) goal date of August 22, 2020. The FDA has indicated that it is currently planning to hold a Cardiovascular and Renal Drugs Advisory Committee (CRDAC) meeting to discuss the application.

42. In addition, the press release quoted Defendant Klaerner, stating:

> "We are rapidly transforming Tricida into a commercial organization that is preparing to launch veverimer, if approved, as the first and only FDA-approved therapy to treat metabolic acidosis and potentially slow CKD progression," said Gerrit Klaerner, Ph.D., Tricida's Chief Executive Officer and President. "We believe there is an urgent need to effectively and safely treat this serious condition. We are working with the FDA to obtain initial approval through the Accelerated Approval Program to market veverimer in the United States."

43. That same day, the Company hosted an earnings call with investors analysts to discuss the Company's fourth quarter 2019 results (the "Q4 2019 Earnings Call"). During the scripted portion of the Q4 2019 Earnings Call, Defendant Klaerner stated:

> . . . the key goal for Tricida in 2020[] [is] the planning and execution of the successful launch of the veverimer. Our PDUFA goal date is just six months away and we are engaged in multiple activities to ensure the successful launch of veverimer in the fourth quarter of this year and sales growth in 2021 and beyond.
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> [W]ith respect to our NDA, we will not be providing updates on our discussions or interactions with the FDA during the review process other than to say that the routine matters around our submission are on the way and we'll continue to work with the FDA to enable them to complete the review in a timely manner. The FDA is planning to hold an advisory committee meeting or AdCom to accept the application.
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> We're anticipating that the outcome would likely occur in the second quarter of 2020 and we'll know the topic of discussion closer to the meeting date. As we said previously, given that we are pursuing a potential disease-modifying indication in

> CKD, utilizing the accelerated approval program we welcome this opportunity and we will be prepared to present the underlying rationale and the considerable body of evidence supporting the treatment of metabolic acidosis closes the progression of kidney disease.
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> In addition, when asked a question regarding Tricida's plans for European filing of veverimer, Defendant Klaerner responded, in relevant part, "[o]ur plans continue to be that we will have substantive engagement with European regulatory authorities starting just after our expected approval in the U.S. So that would be post the August 22nd, PDUFA date."

44. On March 2, 2020, the Company filed an Annual Report on Form 10-K with the SEC, reporting the Company's financial and operating results for the quarter and year ended December 31, 2019 (the "2019 10-K"). The 2019 10-K stated:

> Our [NDA] for veverimer as a chronic treatment for metabolic acidosis in patients with CKD, is currently under review by the U.S. Food and Drug Administration, or FDA, through the Accelerated Approval Program. [. . . .] Results from our positive Phase 3, 12-week efficacy trial, TRCA-301, and a follow on 40-week extension trial, TRCA-301E, formed the primary clinical basis of our NDA submission. The Lancet published the results of the TRCA-301 trial in March 2019 and the results of the TRCA-301E trial in June 2019.
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> We believe the data from our TRCA-301 and TRCA-301E trials provide strong evidence that veverimer can effectively raise serum bicarbonate levels in patients with metabolic acidosis and CKD, and potentially slow progression of CKD as well as provide a clinically meaningful difference in physical function related quality of life and daily physical functioning.

45. In discussing the Company's strategies, the 2019 10-K stated:

> Our strategy is to develop and commercialize veverimer as the first and only FDA approved therapy for the treatment of metabolic acidosis and slowing of kidney disease progression in patients with metabolic acidosis associated with CKD for the large population of patients with metabolic acidosis and CKD. Key elements of our strategy are to:
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> - Obtain FDA approval of veverimer. The veverimer NDA is currently under review through the FDA's Accelerated Approval Program. The FDA has assigned a PDUFA goal date of August 22, 2020 for the potential approval to market veverimer in the United States.

46. In discussing the Company's development program for veverimer, the 2019 10-K stated:

> Our NDA for veverimer is under review by the FDA through the Accelerated Approval Program for potential approval as the first and only FDA-approved therapy for the treatment of metabolic acidosis and slowing of kidney disease progression in patients with metabolic acidosis associated with CKD. It has been assigned a PDUFA goal date of August 22, 2020 for the potential approval to market veverimer in the United States. The FDA has indicated that it is currently planning to hold a CRDAC meeting to discuss the NDA. The key clinical trials included in the NDA are our successful 135-subject, Phase 1/2 trial, TRCA-101, a successful 217-subject, pivotal Phase 3 clinical trial, TRCA-301 and a successful 196-subject, Phase 3 extension trial, TRCA-301E.
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> Both TRCA-101 and the pivotal study, TRCA-301, utilized change from baseline in serum bicarbonate as their primary endpoint. Eligible subjects who completed the 12-week treatment period in the pivotal TRCA-301 trial were invited to continue in our extension trial, TRCA-301E. The primary endpoint of the TRCA-301E trial was the assessment of the long-term safety profile of veverimer versus placebo. We believe that the data from the TRCA-101, TRCA-301 and TRCA-301E clinical trials will provide sufficient clinical evidence of safety and efficacy to support the approval of our NDA for veverimer pursuant to the Accelerated Approval Program.
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> As part of the Accelerated Approval Program, we are currently conducting a confirmatory postmarketing trial, known as the VALOR-CKD trial, or TRCA-303, to evaluate the efficacy and safety of veverimer in delaying CKD progression in subjects with metabolic acidosis. We initiated the VALOR-CKD confirmatory postmarketing trial in the fourth quarter of 2018.

47. Appended to the 2019 10-K as an exhibit were signed certifications pursuant to SOX by Defendants Klaerner and Parker, attesting that, "[t]he information contained in [the 2019 10-K] fairly presents, in all material aspects, the financial condition and results of operations of the Company."

48. On May 7, 2020, the Company issued a press release announcing the Company's first quarter 2020 financial results. The press release included as the Company's "Upcoming Events and Projected Milestones," in relevant part, "Veverimer PDUFA goal date of August 22, 2020[,]" and "[c]ommercial launch of veverimer anticipated in the second half of 2020, which will

include an extensive digital campaign to expand the reach of our promotional efforts for veverimer, if approved."

49. That same day, the Company hosted an earnings call with investors and analysts to discuss the Company's first quarter 2020 results (the "Q1 2020 Earnings Call"). During the scripted portion of the Q1 2020 Earnings Call, Defendant Klaerner stated:

> In our late-cycle meeting with FDA, we took the opportunity to address outstanding review issues. We presented our data and rationale as to why we think veverimer satisfies the requirements for initial approval under the Accelerated Approval Program, including the magnitude and durability of the treatment effect on the surrogate markup serum bicarbonate, demonstrated in the TRCA-301 and TRCA-301E trials.
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> Under the initial approval, we have to ensure that U.S. patients who would be prescribed veverimer, get clinically significant benefit that outweighs the risk of treatment. Overall, while the FDA continues its review, we remain confident that our submission meets the standard for approval through the Accelerated Approval Program.

50. In addition, when asked whether there may be a risk that the FDA would not be comfortable approving a product on the merits of one study, Defendant Klaerner responded:

> . . . obviously we have an accelerated approval. You have to demonstrate a surrogate effect that is likely going to -- reasonably likely going to translate to clinical benefit, and then have the ability to design an outcome trial, which we've done and that outcome trial is ongoing well on its way, and that's very clear. And then on top of it obviously, while that outcome trial is going on for a few years, you also have to ensure that the patients who are getting it on and the initial approval in the U.S. patients are really getting clinical benefit. And those are the two components that -- and the two boxes we need to check and when you look at our back to back Lancet papers, when you look at the safety data, when you look at the efficacy data, both on the surrogate and beyond the surrogate in terms of the physical functioning, the quality-of-life and the objective chair test data, we are very confident that this is a very favorable risk benefit profile.
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> So we don't see -- our read on the overall situation has really not changed and I think we remain confident that the drug will be approved on August 22 and again I think that you're right, this is not oncology that has done a lot of Accelerated Approvals, so we don't have a lot of things to point to, where this has successfully worked. I think that's a fair statement.

51. On May 8, 2020, the Company filed a Quarterly Report on Form 10-Q with the SEC, reporting the Company's financial and operating results for the quarter ended March 31, 2020 (the "Q1 2020 10-Q"). The Q1 2020 10-Q stated:

> Our [NDA] for veverimer as a chronic treatment for metabolic acidosis, is currently under review by the [FDA] through the Accelerated Approval Program. Results from our positive Phase 3, 12-week efficacy trial, TRCA-301, and a follow-on 40-week extension trial, TRCA-301E, formed the primary basis of our NDA submission. The TRCA-301 trial met both its primary and secondary endpoints in a highly statistically significant manner ($p < 0.0001$ for both the primary and secondary endpoints). The TRCA-301E trial met its primary and all secondary endpoints. The Lancet published the results of the TRCA-301 trial in March 2019 and the results of the TRCA-301E trial in June 2019. The FDA has assigned a Prescription Drug User Fee Act, or PDUFA, goal date of August 22, 2020 for the potential approval to market veverimer in the United States.
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> At this time, we do not believe the COVID-19 pandemic has affected our PDUFA goal date of August 22, 2020. We continue to work cooperatively with the FDA on review matters related to our NDA. In the filing communication letter received from the FDA, also referred to as the Day 74 Letter, the FDA indicated that it planned to hold a Cardiovascular and Renal Drugs Advisory Committee, or CRDAC, meeting to discuss the application. In our late cycle meeting with the FDA, held in May 2020, the FDA indicated it currently does not plan to hold a CRDAC meeting to discuss veverimer, due, in part, to the logistical challenges posed by COVID-19. The lack of an advisory committee meeting should not be interpreted to indicate that there are no review issues being discussed with the FDA or that we will receive approval by the PDUFA goal date, if at all. In our late cycle meeting with the FDA, we had an opportunity to address the substantive review issues that have been raised to date. We presented our data and rationale as to why we think veverimer satisfies the requirements for initial approval under the Accelerated Approval Program, including the magnitude and durability of the treatment effect on the surrogate marker of serum bicarbonate demonstrated in the TRCA-301 and TRCA-301E trials and how U.S. patients who would be prescribed veverimer under the initial approval would get clinically significant benefit that outweighs the risk of treatment. While there can be no assurance that the FDA will agree, we remain confident that our submission meets the overall standard for approval under the Accelerated Approval Program.

52. Appended to the Q1 2020 10-Q as an exhibit were signed certifications pursuant to SOX by Defendants Klaerner and Parker, attesting that, "[t]he information contained in [the Q1 2020 10-Q] fairly presents, in all material aspects, the financial condition and results of operations

of the Company."

53. On August 5, 2020, the Company hosted an earnings call with investors and analysts to discuss the Company's second quarter 2020 results (the "Q2 2020 Earnings Call"). During the scripted portion of the Q2 2020 Earnings Call, Defendant Klaerner stated:

> We were and continue to be surprised and disappointed by this notification from the FDA. We will be prepared to address the FDA's outstanding issues and plan to promptly request a Type A meeting, which are granted to typically resolve in a meeting with the FDA within 30 days of our request and submission of operating materials.
>
> We've worked closely with the FDA during the veverimer program to gain approvals of the Accelerated Approval Program. Our goal is to continue this collaborative approach on any issues that the FDA raises in the future. While we will work through any deficiencies cited by the FDA, it is important to note that we continue to believe that the fundamentals of veverimer itself based on our interaction with many expert nephrologists, we believe that veverimer continues to have an attractive compelling and positive benefit risk profile.

54. The statements referenced in ¶¶ 33-53were materially false and misleading because the Company made false and/or misleading statements, as well as failed to disclose material adverse facts about its business, operational and compliance policies. Specifically, the Company made false and/or misleading statements and/or failed to disclose that: (a) its NDA for veverimer was materially deficient; (ii) accordingly, it was foreseeably likely that the FDA would not accept the NDA for veverimer; and (iii) as a result, its public statements were materially false and misleading at all relevant times.

THE TRUTH BEGINS TO EMERGE

55. On July 15, 2020, the Company issued a press release announcing that, on July 14, 2020, the Company received a notification from the FDA, stating that as part of the FDA's ongoing review of the Company's NDA for veverimer: "the FDA has identified deficiencies that preclude discussion of labeling and post marketing requirements/commitments at this time." The company

further stated that "[t]he notification does not specify the deficiencies identified by the FDA."

56. On this news, the Company's stock price fell $10.56 per share, or 40.31%, to close at $15.64 per share on July 16, 2020.

THE TRUTH EMERGES

57. On October 29, 2020, the Company announced an update on its End-of-Review Type A meeting with the FDA regarding the veverimer NDA, advising investors that the Company "now believes the FDA will also require evidence of veverimer's effect on CKD progression from a near-term interim analysis of the VALOR-CKD trial for approval under the Accelerated Approval Program and that the FDA is unlikely to rely solely on serum bicarbonate data for determination of efficacy." Concurrently, the Company disclosed that it "is significantly reducing its headcount from 152 to 59 people and will discuss its commitments with vendors and contract service providers to potentially provide additional financial flexibility."

58. On this news, the Company's stock price fell $3.90 per share, or 47.16%, to close at $4.37 per share on October 29, 2020.

DERIVATIVE AND DEMAND FUTILITY ALLEGATIONS

59. Plaintiff brings this action derivatively in the right and for the benefit of the Company to redress injuries suffered and to be suffered as a direct and proximate result of Defendants' violations of Sections 10(b) and 21D of the Exchange Act, and their breaches of fiduciary duties and other wrongful conduct as alleged herein and that occurred during the Relevant Period.

60. Plaintiff will adequately and fairly represent the interests of Tricida in enforcing and prosecuting its rights and has retained counsel competent and experienced in derivative litigation.

61. Plaintiff is a current owner of the Company stock and has been an owner of Company stock during the Relevant Period. Plaintiff understands his obligation to hold stock throughout the duration of this action and is prepared to do so.

62. Because of the facts set forth herein, Plaintiff has not made a demand on the Board of the Company to institute this action against the Director Defendants. Such demand would be a futile and useless act because the Board is incapable of making an independent and disinterested decision to institute and vigorously prosecute this action.

63. At the time this suit was filed, the Board was comprised of seven (7) members -- Alpern, Bonita, Coufal, Hirsch, Falberg, Klaerner, and Veitinger. Thus, Plaintiff is required to show that a majority of Defendants, *i.e.*, four (4), could not exercise independent objective judgment about whether to bring this action or whether to vigorously prosecute this action.

64. The Director Defendants face a substantial likelihood of liability in this action because they caused the Company to issue false and misleading statements concerning the information described herein. Because of their advisory, executive, managerial, and directorial positions with the Company, the Director Defendants had knowledge of material non-public information regarding the Company and were directly involved in the operations of the Company at the highest levels.

65. The Director Defendants either knew or should have known of the false and misleading statements that were issued on the Company's behalf and took no steps in a good faith effort to prevent or remedy that situation.

66. The Director Defendants (or at the very least a majority of them) cannot exercise independent objective judgment about whether to bring this action or whether to vigorously prosecute this action. For the reasons that follow, and for reasons detailed elsewhere in this

Complaint, Plaintiff did not make (and was excused from making) a pre-filing demand on the Board to initiate this action because making a demand would have been a futile and useless act.

67. Each of the Director Defendants approved and/or permitted the wrongs alleged herein to have occurred and participated in efforts to conceal or disguise those wrongs from the Company's stockholders or recklessly and/or with gross negligence disregarded the wrongs complained of herein and are therefore not disinterested parties.

68. Each of the Director Defendants authorized and/or permitted the false statements to be disseminated directly to the public and made available and distributed to shareholders, authorized and/or permitted the issuance of various false and misleading statements, and are principal beneficiaries of the wrongdoing alleged herein, and thus, could not fairly and fully prosecute such a suit even if they instituted it.

69. Additionally, each of the Director Defendants received payments, benefits, stock options, and other emoluments by virtue of their membership on the Board and their control of the Company.

THE DIRECTOR DEFENDANTS WERE NOT INDEPENDENT

Defendant Klaerner

70. Defendant Klaerner is the CEO and President of the Company. Defendant Klaerner is also a Director of the Company. Defendant Klaerner is not disinterested or independent, and therefore, is incapable of considering demand because Klaerner (as CEO and President) is an employee of the Company who derives substantially all of his income from his employment with Tricida, making him not independent. As such, Klaerner could not independently consider any demand to sue himself for breaching his fiduciary duties to the Company, because that would have exposed him to liability and threaten his livelihood.

71. This lack of independence and financial benefits received by Defendant Klaerner renders him incapable of impartially considering a demand to commence and vigorously prosecute this action. Further, Defendant Klaerner is a defendant in the securities class action entitled *Pardi v. Tricida, Inc., et al.*, Case 5:21-cv-00076-LHK (N.D. Cal.) ("Securities Class Action).

Audit Committee Defendants – Falberg, Bonita and Hirsch

72. Pursuant to the Company's Audit Committee Charter, the members of the Audit Committee are responsible for, *inter alia*:

> Meet to ***review and discuss the annual audited financial statements and quarterly financial statements with management and the Independent Auditor***, including the disclosures under the caption "Management's Discussion and Analysis of Financial Condition and Results of Operations." The Committee shall make a recommendation to the Board as to whether the annual audited financial statements should be included in the Company's Annual Report on Form 10-K.
>
> Discuss earnings press releases, as well as financial information and earnings guidance provided to analysts and ratings agencies.
>
> Review reports to management prepared by the Independent Auditor or Internal Audit, as applicable, and any responses to the same by management.
>
> Be directly responsible for the appointment, compensation, retention, oversight of the work of, and termination of the Independent Auditor. The Committee shall also be responsible for the resolution of disagreements between management and the Independent Auditor regarding accounting and financial reporting. The Independent Auditor shall report directly to the Committee.
>
> Pre-approve all audit and permitted non-audit and tax services to be provided to the Company by the Independent Auditor, subject to the de minimis exceptions for non-audit services which are approved by the Committee prior to the completion of the audit. The Committee may delegate to one or more of its members the authority to grant such pre- approvals, provided that any decisions of such member or members to grant pre- approvals must be presented to the full Committee at its next scheduled meeting.
>
> Obtain and review, at least annually, a report by the Independent Auditor describing: (i) the Independent Auditor's internal quality control procedures; (ii) any material issues raised by the most recent internal quality control review, or peer review, of the Independent Auditor, or by any inquiry or investigation by governmental or professional authorities, within the preceding five years,

respecting one or more independent audits carried out by the Independent Auditor, (iii) any steps taken to deal with any such issues; and (iv) all relationships between the Independent Auditor and the Company. Discuss with the Independent Auditor any issues or relationships disclosed in such report that, in the judgment of the Committee, may have an impact on the competence or independence of the Independent Auditor.

Obtain and review annually, prior to the completion of the Independent Auditor's annual audit of the Company's year-end financial statements (the "Annual Audit"), a report from the Independent Auditor, describing (i) all critical accounting policies and practices to be reflected in the Annual Audit, (ii) all alternative treatments of financial information within generally accepted accounting principles for policies and procedures related to material items that have been discussed with management, ramifications of the use of such alternative disclosures and treatments, and the treatment preferred by the Independent Auditor, and (iii) other material written communications between the Independent Auditor and management, such as any management letter or schedule of unadjusted differences. Review any reports on such topics or similar topics prepared by management. Discuss with the Independent Auditor any material issues raised in such reports.

Review and evaluate the lead audit partner of the Independent Auditor and assure the regular rotation of the lead audit partner, the concurring partner and other audit partners engaged in the Annual Audit, to the extent required by law.

Review the Company's financial reporting processes and internal controls, based on consultation with the Independent Auditor and Internal Audit, as applicable. Such review shall include a consideration of major issues regarding accounting principles and financial statement presentations, including any significant changes in the Company's selection or application of accounting principles, and major issues as to the adequacy of the Company's internal controls and any special audit steps adopted in light of identified deficiencies.

Discuss with the Independent Auditor the Independent Auditor's judgment about the quality, not just the acceptability, of the accounting principles applied in the Company's financial reporting.

Discuss with the Independent Auditor the Independent Auditor's judgment about the competence, performance and cooperation of Internal Audit and management.

Discuss with Internal Audit and management their views as to the competence, performance and independence of the Independent Auditor.

Review with the Independent Auditor any audit problems or difficulties and management's response thereto. The review should include discussion of the responsibilities, budget and staffing of Internal Audit, as applicable.

Review with the Independent Auditor, Internal Audit and management the extent to which any previously-approved changes or improvements in financial or accounting practices and internal controls have been implemented.

Review and approve any transaction between the Company and any related person (as defined in Item 404 of Regulation S-K) in accordance with the Company's related party transaction approval policy.

Review annually the effect of legal, regulatory and accounting initiatives on the Company's financial statements.

Review annually the effect of off-balance sheet arrangements, if any, on the Company's financial statements.

Review and discuss with the Independent Auditor the matters required to be discussed by the applicable requirements of the Public Company Accounting Oversight Board regarding communications with audit committees.

Overseeing the Company's risk assessment and risk management process with respect to financial reporting, trading in the Company's securities, fraud, healthcare compliance, privacy and cyber-security, it being understood that it is the job of management to assess and manage the Company's exposure to risk and that the Committee's responsibility is to discuss guidelines and policies by which risk assessment and management are undertaken.

Set clear hiring policies for employees or former employees of the Independent Auditor and oversee the hiring of any personnel from the Independent Auditor into positions within the Company in accordance with the hiring restrictions of the Sarbanes-Oxley Act of 2002.

Establish procedures for (i) the receipt, retention and treatment of complaints received by the Company regarding accounting, internal accounting controls, or auditing matters and (ii) the confidential, anonymous submission by employees of the Company of concerns regarding questionable accounting or auditing matters. Review periodically with management and Internal Audit these procedures and any significant complaints received.

Meet separately, periodically, with management, with Internal Audit and with the Independent Auditor.

Review periodically with the Company's Chief Legal Officer and the Chief Compliance Officer, as appropriate, the Company's compliance with legal and regulatory requirements and the Company's major litigation risk exposures and the steps taken by management to monitor and control such exposures.

> Prepare the report of the Committee required to be included in the Company's annual report or proxy statement.
>
> Report regularly to the Board, both with respect to the activities of the Committee generally and with respect to any issues that arise regarding the quality or integrity of the Company's financial statements, the Company's compliance with legal and regulatory requirements, the performance and independence of the Independent Auditor or the performance of Internal Audit.
>
> Conduct an annual performance evaluation of the Committee and its members, including a review of adherence to this Charter.
>
> Review the adequacy of this Charter annually and recommend any proposed changes to the Board for approval.
>
> Perform such other duties and responsibilities, consistent with this Charter, the Company's bylaws, governing law, the rules and regulations of NASDAQ, the federal securities laws and such other requirements applicable to the Company, delegated to the Committee by the Board.

73. Defendants Falberg, Bonita and Hirsch breached their fiduciary duties of due care, loyalty, and good faith, because the Audit Committee, *inter alia*, allowed or permitted false and misleading statements to be disseminated in the Company's SEC filings and other disclosures and, otherwise failed to ensure that adequate internal controls were in place regarding the serious business reporting issues and deficiencies described above. Therefore, Defendants Falberg, Bonita and Hirsch face a substantial likelihood of liability for their breach of fiduciary duties and any demand upon them is futile.

Defendant Veitinger

74. Defendant Veitinger has served as a Venture Partner with OrbiMed Advisors LLC ("OrbiMed"), an affiliate of one of the Company's principal stockholders, since October 2007.

75. OrbiMed owns 19.3% percent of outstanding shares of the Company.

Defendant Coufal

76. Defendant Coufal is a co-founder and has served as a comanager of Sibling Capital

Ventures LLC, an affiliate of one of the Company's principal stockholders, since 2013.

77. Sibling owns 12.9% percent of the outstanding shares of the Company.

COUNT I

(Against Defendants Klaerner and Parker for Violations of Sections 10(b) and 21D Of The Exchange Act)

78. Plaintiff incorporates by reference and realleges each and every allegation contained above, as though fully set forth herein.

79. The Company, along with Defendants Klaerner and Parker are named as defendants in the Securities Class Actions, which assert claims under the federal securities laws for violations of Sections 10(b) and 20(a) of the Exchange Act, and SEC Rule 10b-5 promulgated thereunder. If and when the Company is found liable in the Securities Class Actions for these violations of law, the Company's liability will be in whole or in part due to Defendants Klaerner and Parker's willful and/or reckless violations of their obligations as officers and directors of the Company.

80. Through their positions of control and authority as officers of the Company, Defendants Klaerner and Parker were able to and did, directly and/or indirectly, exercise control over the business and corporate affairs of the Company, including the wrongful acts described in the Securities Class Action and herein.

81. As such, Defendants Klaerner and Parker are liable under 15 U.S.C. § 78j(b), which creates a private right of action for contribution, and Section 21D of the Exchange Act, 15 U.S.C. § 78u- 4(f), which governs the application of a private right of action for contribution arising out of violations of the Exchange Act.

COUNT II

(Against the Director Defendants for Breach of Fiduciary Duty)

82. Plaintiff incorporates by reference and realleges each and every allegation

contained above, as though fully set forth herein.

83. The Director Defendants owed the Company fiduciary obligations. By reason of their fiduciary relationships, the Director Defendants owed the Company the highest obligation of good faith, fair dealing, loyalty, and due care.

84. The Director Defendants violated and breached their fiduciary duties of care, loyalty, reasonable inquiry, and good faith.

85. The Director Defendants engaged in a sustained and systematic failure to properly exercise their fiduciary duties. Among other things, the Director Defendants breached their fiduciary duties of loyalty and good faith by permitting the use of inadequate practices and procedures to estimate its reserves set aside for annuity and pension payments, allowing or permitting false and misleading statements to be disseminated in the Company's SEC filings and other disclosures and, otherwise failing to ensure that adequate internal controls were in place regarding the serious business reporting issues and deficiencies described above. These actions could not have been a good faith exercise of prudent business judgment to protect and promote the Company's corporate interests.

86. As a direct and proximate result of the Director Defendants' failure to perform their fiduciary obligations, the Company has sustained significant damages. As a result of the misconduct alleged herein, the Director Defendants are liable to the Company.

87. As a direct and proximate result of the Director Defendants' breach of their fiduciary duties, the Company has suffered damage, not only monetarily, but also to its corporate image and goodwill. Such damage includes, among other things, costs associated with defending and/or settling securities lawsuits and governmental investigations, severe damage to the share price of the Company's stock, resulting in an increased cost of capital, and reputational harm.

COUNT III

(Against the Director Defendants for Waste of Corporate Assets)

88. Plaintiff incorporates by reference and realleges each and every allegation contained above, as though fully set forth herein.

89. The wrongful conduct alleged regarding the issuance of false and misleading statements was continuous, connected, and on-going throughout the Relevant Period. It resulted in continuous, connected, and ongoing harm to the Company.

90. As a result of the misconduct described above, the Director Defendants wasted corporate assets by, *inter alia*: (a) paying excessive compensation, bonuses, and termination payments to certain of its executive officers; (b) awarding self-interested stock options to certain officers and directors; and (c) incurring potentially millions of dollars of legal liability and/or legal costs to defend and/or settle actions addressing Defendants' unlawful actions.

91. As a result of the waste of corporate assets, the Director Defendants are liable to the Company.

92. Plaintiff, on behalf of the Company, has no adequate remedy at law.

PRAYER FOR RELIEF

WHEREFORE, Plaintiff prays for relief and judgment, as follows:

(A) Declaring that Plaintiff may maintain this action on behalf of the Company and that Plaintiff is an adequate representative of the Company;

(B) Finding Defendants liable for breaching their fiduciary duties owed to the Company;

(C) Directing Defendants to take all necessary actions to reform and improve the Company's corporate governance, risk management, and internal operating procedures to comply

with applicable laws and to protect the Company and its stockholders from a repeat of the rampant wrongful conduct described herein;

(D) Awarding damages to the Company for the harm the Company suffered as a result of the Defendants' wrongful conduct;

(E) Awarding damages to the Company for Defendants Klaerner and Parker's violations of Sections 10(b) and 21D of the Exchange Act;

(F) Awarding Plaintiff the costs and disbursements of this action, including attorneys', accountants', and experts' fees; and

(G) Awarding such other and further relief as is just and equitable.

JURY TRIAL DEMANDED

Plaintiff hereby demands a trial by jury on all issues so triable.

Dated: February 15, 2021

BIELLI & KLAUDER, LLC

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